K001746

JUL 1 9 2000

Attachment 6

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness for the LightSheer™ Pulsed Diode Array Laser System is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(k) summary.

Applicant:	Coherent Star
Address:	1249 Quarry Lane, Suite 100 Pleasanton, CA 94566
Contact Person:	Ilirija Encinas
Telephone:	(925) 249-8031
Preparation Date:	June 5, 2000
Device Trade Name:	LightSheer™ Pulsed Diode Array Laser System
Common Name:	Pulsed Diode Array Laser
Classification Name:	Laser surgical instrument for use in General and Plastic Surgery and in Dermatology (see 21 CFR 878.4810). Product Code: GEX Panel: 79
Legally-Marketed Predicate Device:	Palomar Medical Technologies, Inc. SLP 1000™, Diomed LaserLite™, Iris/Iriderm DioLite™ 532, Continuum Biomedical CB Diode/532™, and ESC Medical Systems/Sharplan PhotoDerm® MultiLight™.
System Description:	The LightSheer system delivers pulsed infrared laser light with a wavelength of nominally 800 nm, a selectable pulse duration of 5 – 200 ms, and a selectable fluence of 10 – 60 J/cm^2. The corresponding pulse energy delivered through the 9 x 9 mm handpiece tip in some models, and the

	12 x 12 mm handpiece tip in others, is 8 - 32 J and 14 - 90 J respectively. The laser pulses are capable of generating a maximum pulse repetition frequency of 3 Hz by several arrays of diode lasers located in the handpiece. The complete system consists of a console, a footswitch, and a handpiece connected to the console with an umbilical. In standard use, the handpiece is pressed against the patient's skin and a light pulse is delivered when the footswitch and handpiece trigger are depressed. The handpiece tip is water-cooled to provide active skin cooling. Laser parameters and other system features are controlled from the touch-screen on top of the console, which provides an interface to the system computer.
Intended Use of the Device:	The LightSheer Pulsed Diode Array Laser System is intended for the treatment of benign pigmented lesions in dermatology and plastic surgery procedures. The LightSheer is also indicated for hair removal, permanent hair reduction, and the treatment of leg veins in all skin types (Fitzpatrick I-VI), including tan skin.
Performance Data:	None. The specifications and indications for use of the LightSheer Pulsed Diode Array Laser System are the same or very similar to those of the claimed predicate devices. The LightSheer Pulsed Diode Array Laser System has the same indications for use for which the claimed predicates have been cleared. Because of this, performance data were not required.
Conclusion:	Based on the foregoing, the LightSheer Pulsed Diode Array Laser System is substantially equivalent to the legally-marketed claimed predicate device for the purposes of this 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2000

Ms. Ilirija Encinas
Clinical Affairs Coordinator
Coherent Star
1249 Quarry Lane, Suite 100
Pleasanton, California 94566

Re: K001746
Trade Name: LightSheer Pulsed Diode Array Laser System
Regulatory Class: II
Product Code: GEX
Dated: June 5, 2000
Received: June 8, 2000

Dear Ms. Encinas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: ~~Pending~~ K001746

Device Name: LightSheer Pulsed Diode Array Laser System

Indications for Use:

The LightSheer Pulsed Diode Array Laser System is intended for the treatment of benign pigmented lesions in dermatology and plastic surgery procedures.

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001746

Prescription Use ✓ OR Over-the-Counter Use ___
(per 21 CFR 801.109)